

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	JAMES J. PAGLIUCA et al.	Confirmation No.:	8425
Serial No.:	10/665,754	Examiner:	VICTOR X. NGUYEN
Filed:	SEPTEMBER 19, 2003	Group Art Unit:	3734
Docket No.:	1291.1139101	Customer No.:	33469
Title:	SURGICAL TOOL FOR USE IN EXPANDING A CANNULA		

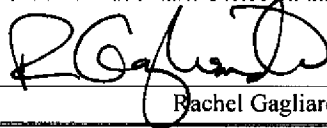
PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP: Appeal Brief
Commissioner for Patents
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The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 27th day of January 2009.

By



Rachel Gagliardi

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 1, 3-5, 7, 9-12, 14, 16-18, and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Nwawka (U.S. Patent No. 6,036,638). Nwawka fail to teach the identical structure in the same arrangement as recited in the independent claims, thus the rejection is made in error.

In the final Office Action, on page 2, the Examiner asserts that Nwawka teaches an expandable tubular structure 103 and "a surgical tool structured 20 is able to expand the tubular structure, where the tool includes *an elongate body 100* and a first leg at 30, a second leg at 40." The Examiner appears to have misinterpreted the reference. Nwawka teaches, "speculum 20 comprises a lower arm 30, an upper arm 40, and a pivot mechanism 50" (see column 4, lines 25-26 and FIG. 1), and "vaginal sleeve 100, designed to envelope a conventional bi-valve vaginal speculum 20, comprises sheath 103" (see column 5, lines 42-44, and FIG. 2). Nwawka thus teaches

the speculum 20 includes arms 30 and 40, while the vaginal sleeve 100 comprises a sheath 103. The Examiner's reference to a tool 20 that includes an elongate body 100 and a first leg at 30 and a second leg at 40 is not disclosed by Nwawka. Nwawka clearly teaches the speculum 20 comprising a lower arm 30 and upper arm 40. Nwawka does not appear to teach sleeve 100 having any arms. Nwawka also teaches the relationship between the speculum 20 and sleeve 100 as, "the gynecologist or obstetrician would slide the proximal end 160 of vaginal sleeve 100 over speculum arms 30, 40." See column 6, lines 21-23. Nwawka thus teaches the sleeve 100 as a separate device that, in use, is fitted over the speculum 20 with arms 30, 40. One of ordinary skill in the art would not interpret the speculum 20 with arms 30, 40 and the separate sleeve 100 as being in any way the same element. Further, one of ordinary skill in the art would not interpret the sleeve 100 of Nwawka as having any arms, and certainly not arms 30, 40, which are clearly described as being part of speculum 20.

In the Advisory Action mailed January 14, 2008, the Examiner asserts that "as seen in fig 4 of Nwawka, it is possible the vaginal sleeve or a shaft 100 designed to envelop a speculum 20." The Examiner appears to have acknowledged that Nwawka teaches elements 100 and 20 as a separate sleeve and speculum. It is thus not understood how the rejection can be maintained as the reference clearly does not teach the identical structure as recited in the claims. As discussed above, the vaginal sleeve or shaft 100 of Nwawka is a separate element from the speculum 20, and it is the speculum 20 which has the arms 30, 40, and not the sleeve 100 as asserted by the Examiner. The sleeve 100 thus cannot be seen to be the element having arms 30, 40.

The Examiner appears to be asserting different parts of two separate and distinct devices of Nwawka as meeting the structural elements of a single device as recited in the claims. Applicants submit such an interpretation is improper. MPEP § 2131 states:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir.

1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Emphasis added. Applicants submit that Nwawka fail to teach every element arranged as required by independent claim 1, and thus Nwawka cannot be deemed to anticipate the claim and the rejection is made in error.

The Examiner asserts, in the final Office Action on page 2, that “the actuator 90 at best seen in fig. 1 definitely is able to move axially with the elongate body of the surgical tool which moves the first and the second legs away from each other.” In view of the fact that the Examiner previously asserted that sleeve 100 of Nwawka is considered the elongate body, this statement is not understood. Nwawka teach “thumb press 90 connected to the proximal end 44 of the upper arm 40.” See column 5, lines 6-7 and FIG. 1. While the thumb press 90 appears to move arms 30 and 40 away from each other, Nwawka does not appear to teach the thumb press 90 as moving axially with regard to any structure. In particular, Nwawka does not appear to teach the thumb press 90 moving axially with the sleeve 100.

Regarding independent claim 10, the Examiner again appears to be equating elements from the vaginal sleeve 100 as being part of the speculum 20. The Examiner asserts that Nwawka teaches an intermediate member 105. The Examiner appears to be asserting that speculum 20 of Nwawka reads on the claimed elongate member, and the vaginal sleeve 100 reads on the claimed expandable tubular structure. However, the Examiner’s assertion that Nwawka teach an intermediate member 105 is not supported by the reference. Nwawka teach the vaginal sleeve, including the sheath 103, as further comprising ribs 105. See column 6, line 1 and FIG. 2. The ribs 105 are thus part of the sleeve 100 or sheath 103, and not the speculum 20. As discussed above, an anticipation rejection requires the elements in a reference to be arranged as required by the claim. Nwawka do not appear to recite the identical elements in the same arrangement as recited in independent claim 10, thus the rejection is in error. Withdrawal of the rejection is respectfully requested.

Regarding independent claim 16, and as stated in the previous response, the Office Action does not state which elements of Nwawka teach the limitations of claim 16. In the Advisory Action, the Examiner referred to page 3, lines 15-18 of the final

Office Action for a discussion of claim 16. This section of the Office Action states, “Nwawka discloses the surgical tool assembly as claimed in claim 1 as discussed above including a handle *pivotally at 76* which connected to the first end of the shaft and where the first and second jaw *pivotally at 74* which connected to the second end of the shaft”. As stated in the previous response, the Examiner has not indicated which element of Nwawka is interpreted as being the shaft. Based on the Examiner’s assertion that a handle is pivotally connected to a first end of the shaft at 76 and first and second jaws are pivotally connected to the second end of the shaft at 74, the element in Nwawka asserted to be the shaft cannot be determined. As shown in FIG. 1, Nwawka does not appear to teach a shaft having a first end connected to a handle at 76 and a second end connected to first and second jaws at 74. Nwawka appears to teach two jaws 30, 40, and two handle portions 38, 90, where handle 90 appears to be integrally formed on jaw 40. The device and elements of Nwawka do not appear to have the identical structure and be in the same arrangement as recited in the claims. Nwawka, therefore, does not appear to teach each and every limitation of claim 16.

Applicants assumed, for the sake of argument, that the limitation of “first and second jaws pivotally connected to the second end of the shaft” occurs at pin 76 of Nwawka, only one jaw (upper arm 40) could be considered to be pivotally connected at pin 76. (“The proximal end 44 of the upper arm 40 is pivotally connected to the first and second pins 74, 76.” (Fig. 1; col. 4 lines 63-65).) On the other hand, assuming, for the sake of argument, that the limitation of “first and second jaws pivotally connected to the second end of the shaft” occurs at pivot mechanism 50 of Nwawka, at best only the second jaw (lower arm 30) could be deemed to pivotally connect at pivot mechanism 50. (“The lower arm 30 comprises a blade 32 having a proximal end 34, a distal end 36, and a handle portion 38 which is integrally connected to the proximal end 34 of the blade 32.” (Fig. 1; col. 4, lines 27-29).) Also, according to claim 16, the handle is pivotally connected to the *first end* of the shaft. The only apparent possible locations for a pivotal connection of a handle, according to Nwawka, would be pin 76 which was previously established to be at the *second end* of the shaft since the first jaw is pivotally connected there, or at pivot mechanism 50 which would also be the

second end since the second jaw was connected through the handle portion 38. (Fig.

1). Nwawka does not teach the identical structure as recited in the claims. The rejection is thus made in error.

Claims 6, 8, 13, 15, and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nwawka (U.S. Patent No. 6,036,638) in view of Gerrone (U.S. Patent No. 5,312,351). This rejection was repeated from the previous Office Action, but the Examiner has not addressed Applicants' previous remarks. Applicants submit that the Examiner's failure to respond while repeating the rejection is an error. MPEP 707.07(f) states, "[w]here the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." Applicants submit that because the Examiner has not questioned or responded to Applicants' previous arguments, it appears the Examiner has accepted the arguments. Maintaining the rejection is thus in error.

Further, as discussed above, Nwawka does not appear to teach each and every limitation of independent claims 1, 10, and 16. Gerrone does not appear to cure the failings of Nwawka. Claims 1, 10, and 16, therefore, are believed patentable over Nwawka in view of Gerrone. As claims 6, 8, 13, 15, and 19 depend from claims 1, 10, and 16 and add further limitations thereto, Applicants also believe that claim 6, 8, 13, 15, and 19 are patentable over Nwawka in view of Gerrone. For at least the reasons set forth above, the rejection is also made in error.

If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

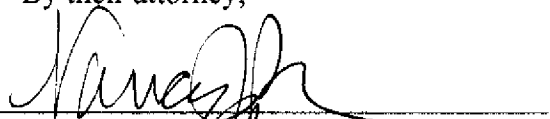
Respectfully submitted,

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By their attorney,

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1/27/09



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